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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,867	10/25/2000	Mary E. Brunkow	240083.501D6	2612

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EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 10/22/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/696,867

Applicant(s)

BRUNKOW ET AL.

Examiner

Sumesh Kaushal Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 34,35 and 37-39 is/are rejected.
- 7) ☐ Claim(s) 36, 40-42 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____

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DETAILED ACTION

Applicant's response filed on 07/24/02 has been acknowledged.

Claims 35-42 were newly filed.

Claim 34 was amended.

Claims 34-42 were pending and were examined in this office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

► *If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED.*

Claim Rejections - 35 USC § 112

Claim 34-35 and 37-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic scurfy mouse whose cells express a transgene that contain a sequence encoding mouse Fkh^{sf} protein wherein the expression of exogenous Fkh^{sf} transgene results in reduction of T-lymphocyte proliferation in the mouse, does not reasonably provide enablement for any and all transgenic non-human mammals whose cells express a transgene the contain a Fkh^{sf} coding sequence obtained from any and animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons of record as set forth in the office action mailed on 06/05/02.

The applicant argues that making any and all non-human transgenic animals encoding Fkh^{sf} transgene does not requires undue amount of experimentation. The applicant further argues that mere fact that some experimentation is necessary does not negate enablement as long as undue experimentation is not required. The applicant concluded that even low range of transgene efficiency does not lead to conclusion of undue experimentation in production of transgenic mammals.

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However, this is not found persuasive because applicant's argument alone cannot take place of evidence lacking in the record (see *In re Scarbrough* 182 USPQ, (CCPA) 1979). The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). At best the specification is only enabled for a transgenic scurfy mouse whose cells express a transgene that contain a sequence encoding mouse Fkh^{sf} protein wherein the expression of exogenous Fkh^{sf} transgene results in reduction of lymphocyte proliferation in the mouse. The instant specification fails to provide any guidance to make all non-human mammals encoding the Fkh^{sf} transgene.

The scope of invention as claimed encompasses any and all non-human transgenic mammals whose cells express a transgene that contain a sequence encoding Fkh^{sf} protein. The scope of non-human transgenic mammals encompasses any and all mammals like whale, pig, dog cats cow, monkey and elephant etc.). Besides a transgenic mouse the instant specification fails to disclose any other transgenic mammal whose cells express a transgene that contain a sequence encoding Fkh^{sf} protein, wherein the sequence encoding Fkh^{sf} transgene has been obtained from any and all organisms. The state of transgenic art at the time of filing was such that making a transgenic mammal is considered highly unpredictable, since phenotype of an animal is determined by a complex interaction of genetics and environment. Furthermore, the transgene expression and physiological consequences of transgene products in non-mouse mammals are not always accurately predicted among various species of mammals (see pages 2-5, Paper No.7, Office action mailed on 06/05/02). ***Making transgenic mammals selected from any and all mammalian species is not considered routine in the art and without sufficient guidance to a specific therapeutic gene the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.*** See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). It is noted that the unpredictability of a particular area may alone provide reasonable doubt as to the accuracy of the broad statement made in support of enablement of claims. See *Ex parte Singh*, 17 USPQ2d 1714 (BPAI 1991).

In addition, newly filed claims 35 and 37-39 stand rejected because instant claims fail to recite the required phenotype (*wherein the Fkh^{sf} transgene results in reduction of T-lymphocyte proliferation in the mouse*) which would guide one skill in the art how to use the claimed

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transgenic mouse invention. In corporation of the claim limitation as recited in claim 36 into the base claim 35 would overcome this rejection.

Therefore, one skill in the art would have to engage in excessive and undue amount of experimentation to exercise the invention as claimed. The quantity of experimentation required would include making of any and all non-human transgenic mammals (like a whale, a pig, a dog, a cat, a cow, a monkey and an elephant etc) encoding a transgene that contains a Fkh^{sf} coding sequence obtained from any and all organisms. The amount of experimentation required would further include phenotypic characterization of scurfy phenotypes across variety of mammals and phenotypic evaluation of the Fkh^{sf} transgenic mammals, wherein the Fkh^{sf} transgene has been obtained from any and all organisms.

Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 is indefinite because it is unclear what is reduction of lymphocytes. It is unclear whether the reduction as claimed is, reduction in size of lymphocytes or number of lymphocytes.

Conclusion

No claims are allowed

Claims 36, 41-42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitation of the base claim and any intervening claims.

The art at the time of filing does not teach or suggest "A transgenic mouse whose cells express a transgene that contains a sequence encoding mouse Fkh^{sf} protein wherein the expression of exogenous Fkh^{sf} transgene results in reduction of T-lymphocyte proliferation in the mouse".

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is (703) 305-6838. The examiner can normally be reached on Monday-Friday from 9:00 AM to 5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Irem Yucel Ph.D. can be reached on (703) 305-1998. The fax-phone number for the organization where this application or proceeding is assigned as (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst Zeta Adams, whose telephone number is (703) 305-3291.

S. Kaushal
Patent examiner

SCOTT D. PRIEBE, Ph.D.
PRIMARY EXAMINER

Scott D. Priebe